
# Ethics of Fetal Tissue Transplantation

LEE M. SANDERS, LINDA GIUDICE, MD, PhD, *and* THOMAS A. RAFFIN, MD, *Stanford, California*

**Now that the Clinton Administration has overturned the ban on federal funding for fetal tissue transplantation, old ethical issues renew their relevance and new ethical issues arise. Is fetal tissue transplantation necessary and beneficial? Are fetal rights violated by the use of fetal tissue in research? Is there a moral danger that the potential of fetal tissue donation will encourage elective abortions? Should pregnant women be allowed to designate specific fetal transplant recipients? What criteria should be used to select fetal tissue transplants? Whose consent should be required for the use of fetal tissue for transplantation? We review the current state of clinical research with fetal tissue transplantation, the legal history of fetal tissue research, the major arguments against the use of fetal tissue for transplantation, and the new post-moratorium ethical dilemmas. We include recommendations for guidelines to govern the medical treatment of fetal tissue in transplantation.**

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Human fetal tissue transplantation is still experimental, and trials with animals and humans have shown limited success. But researchers and clinicians agree that, given social and legal support, fetal tissue transplants could soon promise unique therapy for dozens of crippling diseases with substantial morbidity and mortality. Clinical trials with human fetal tissue have already been conducted on patients with Parkinson's disease, insulin-dependent diabetes mellitus, the DiGeorge syndrome, severe combined immunodeficiency, aplastic anemia, acute myelogenous leukemia, thalassemia, Fabry's disease, the Hurler syndrome, and Gaucher's disease. Others have proposed that fetal tissue be used to treat Alzheimer's disease, congenital heart failure, congenital liver failure, congenital kidney failure, and a host of hematologic and endocrine abnormalities in adults and children. The patient population that could benefit from fetal tissue transplants is substantial.

Since *Roe versus Wade* legalized abortion in 1973, pregnant women and their developing fetuses have been at the center of one of the most heated public debates in American history. Scientific journals have steered clear of such politically charged controversy, and several federal panels have found vague language to evade moral stances on abortion. But the promise of fetal tissue therapy in a shifting political climate makes clear the need for opinions to be voiced frankly by the medical community.

We strongly favor the use of human fetal tissue for the purposes of medical therapy, and herein we discuss the current state of clinical research with fetal tissue transplantation, the legal history of fetal tissue research in the United States, the major arguments against fetal tissue transplantation, and a framework for solving ethical problems involving aborted fetuses. We conclude by proposing a set of ethical guidelines to govern medical uses of human fetal tissue.

## Using Fetal Tissue for Transplantation

Fetal tissue transplantation may be able to overcome the failures of traditional medical and surgical therapy to ameliorate several diseases, most notably Parkinson's disease and insulin-dependent diabetes mellitus. Furthermore, the use of fetal tissue may be required to develop novel therapies for hematolymphoid diseases.

### *Medical and Surgical Alternatives*

Medical alternatives to fetal tissue transplantation are currently being refined, but long-term cures remain elusive. Most persons with insulin-dependent diabetes currently use genetically engineered human insulin, combined with careful dietary management, to control blood glucose levels. Even with good glucose control, however, the disease progresses, and patients have a relatively early onset of peripheral neuropathy, nephropathy, retinopathy, and heart disease. Patients with Parkinson's disease derive some benefit from the drug levodopa, a congener of dopamine, but even with medication, they continue to ex-

From the Stanford University Center for Biomedical Ethics, Stanford University School of Medicine, Stanford, California.

Reprint requests to Thomas A. Raffin, MD, Co-Director, Stanford University Center for Biomedical Ethics, Stanford University Medical Center, Stanford, CA 94305-5236.

**ABBREVIATIONS USED IN TEXT**
NIH = National Institutes of Health
UAGA = Uniform Anatomical Gift Act

perience "on-off" episodes of neuromuscular control, and many young persons lose their ability to function at work and at home. Although multidrug trials with chemotherapy and radiotherapy hold promise for some hematolymphoid diseases, most of these diseases eventually resist medical treatment.

Surgical alternatives are overshadowed by unsatisfactory results and long-term requirements for immunosuppression. Some patients with Parkinson's disease have received autografts and allografts of adrenal medullary cells and xenografts of modified adrenal medullary cells from rodents and primates.[1] Many surgical protocols, however, particularly in the field of adrenal allografts, have been suspended in response to unpromising results.[2] Hematopoietic stem cell replacement is a possible therapy for some immunodeficiencies and hematologic cancers, but the research—much of which uses fetal tissue—is in its infancy.[3]

Although initially hopeful, pancreatic allograft and xenograft results provide little comfort for persons newly diagnosed with diabetes. And although the possibility of isolated islet cell xenografts is being actively pursued, no permanent success has yet been reported.[4] More than 3,000 persons with diabetes have received pancreas transplants during the past 26 years, and the most recent transplants have produced insulin-independent life-styles for 72% of the recipients. Unfortunately, all recipients require immunosuppressive medication, and the one-year mortality rate is about 8%.[5] Thus far, only persons with diabetes who have received kidney transplants and those who are severely impaired are considered for pancreas transplants. As a result, the long-term ability of these allografts to prevent the onset of the diabetic morbidity is untested.

*Principles of Fetal Tissue Transplantation*

Human fetal tissue is an attractive source of therapeutic transplants because it has two physiologic properties that make it more useful than adult or animal tissue. First, most fetal cells are hyperproliferative and multipotent, meaning that these donor cells are capable of quickly reversing the lost function of a host organ. Second, fetal cells may pose a low immunogenic threat to the cellular defenses of the host.[6,7] Current experiments with adult donor tissue are often limited by deficiencies in these properties.

Research on fetal tissue to develop medical therapy is not new. Fetal tissue research was responsible in the 1950s and 1960s for vaccines against polio and rubella, the treatment of Rh incompatibility, and the prenatal diagnosis of genetic diseases. But the use of fetal tissue as a means of medical therapy is new. Clinical trials with fetal neural, thymic, pancreatic, and hematopoietic tissue are underway internationally.

*Fetal Tissue Transplantation in Humans*

The only recorded successes with fetal tissue transplantation in humans are in treating Parkinson's disease[7-11] and a rare congenital disorder, DiGeorge syndrome.[12] The most accepted theory to explain Parkinson's disease attributes its cause to a relative deficiency of dopamine produced in the nigrostriatal region of a patient's brain. Operating on this theory since 1987, surgeons have transplanted dopamine-producing neural tissue from first-trimester abortuses into the brains of patients with Parkinson's disease. Results with 13 patients in three separate studies vary according to surgical technique and patient selection, but fetal tissue transplantation does improve self-assessed quality of life; it decreases the frequency and intensity of "freezing spells"—a characteristically disabling feature of the disease—and decreases the required dosage of levodopa.[8-10]

For more than 20 years patients with DiGeorge syndrome, an immunodeficiency resulting from the absence of thymus and parathyroid tissue at birth, have been known to respond well to transplants of fetal thymus tissue.[12]

Preliminary results with fetal tissue transplantation for other human diseases show little success. Fetal pancreatic tissue has been shown to reduce exogenous insulin requirements in humans with insulin-dependent diabetes, but only transiently.[13] Because fetal liver tissue is a robust source of pluripotent hematolymphoid cells, it has been used experimentally to treat hemophilia, severe combined immunodeficiency, aplastic anemia, and acute myelogenous leukemia. These treatments have produced minimal success, but most have been done late in the natural progression of the disease, after standard chemotherapeutic trials have failed.[10] In utero transplants to treat hematologic and immune deficiencies are being widely investigated in animals[14,15] and in humans.[16-18] Several medical and scientific organizations have concluded that fetal tissue transplantation will be a vital part of cellular therapy in years to come.[10]

*Need for Tissue From Elective Abortions*

During a 1991 Senate debate, the Bush Administration proposed an amendment that established a national network of tissue banks authorized to store only tissue from spontaneously aborted fetuses and ectopic pregnancies.[15] The tissue bank, administered through five national centers, cost $6 million to establish.[19] For logistical reasons, however, future success in human fetal tissue transplantation cannot depend on tissue from spontaneous abortions, stillbirths, and ectopic pregnancies. Unlike that from elective abortions, tissue from at least 60% of spontaneous abortions contains severe genetic defects. Even without genetic defects, a large percentage of these fetuses do not have enough differentiated tissue to be therapeutically useful. Of spontaneous abortions, only 3.8% (or about 28,000 fetuses) each year would provide tissue theoretically eligible for transplantation, but this figure includes many fetuses that are practically ineligible for transplantation because they died much earlier in utero or

because they were never karyotyped to rule out trisomy. Of ectopic pregnancies, 21% to 49% (18,000 to 43,000) are morphologically intact, but only 1% (880) are unassociated with tubal hemorrhage, a common cause of early organ death in fetuses.[20] The combined conservative total represents less than a third of the annual population diagnosed in the United States with Parkinson's disease and insulin-dependent diabetes mellitus. This low yield, combined with the burden of obtaining specimens from unscheduled events that often occur at home or in an emergency department, makes transplantable tissue from spontaneous abortions and ectopic pregnancies effectively inaccessible.

## Legal History of Fetal Tissue Research

Although fetal tissue transplantation has been experimental in the United States since the 1930s, legal controversy over fetal tissue research did not arise until immediately after the Supreme Court's *Roe versus Wade* decision. On April 12, 1973, a 200-person protest organized by a Catholic girls' school persuaded a National Institutes of Health (NIH) official to voice publicly the government's opposition to the use of "live" fetal tissue for research. The next day, New York Representative Angelo Roncallo introduced legislation to ban all fetal tissue research in the United States.[21]

Political action on fetal tissue research remained dormant until March 1988, when Robert Windom, President Reagan's Assistant Secretary of Health and Human Services under Otis Bowen, imposed a moratorium on fetal tissue research for transplantation purposes, pending the recommendations of a 21-member NIH panel. After two days of public hearings and three months of deliberation, the panel concluded that funding human fetal tissue transplantation was acceptable public policy. Despite such institutional support for fetal tissue research, Secretary of Health and Human Services Louis Sullivan extended indefinitely the moratorium on federal funding of fetal tissue research for transplantation.

Separate measures to overturn the funding moratorium, appended to an NIH appropriations bill, passed in the House of Representatives in 1991 and in the Senate in 1992. Senate support was heavily influenced by personal appeals, including Republican Strom Thurmond's plea on behalf of his daughter, who has diabetes.[22] New legislation would have funded research on tissue donated from elective abortions, subject to clear evidence that "the decision to make the donation is made separately and independently of the decision to undergo the abortion."[23] But Senate filibustering at the end of the last congressional session in 1992 allowed the bill's demise.

Soon after taking office in 1993, President Clinton overturned by executive order the moratorium on federally funded fetal tissue transplantation. Since then, there has been a notable increase in grant applications to the NIH for proposals to use fetal tissue in experimental transplantation, and Congress is authorizing the Department of Health and Human Services to oversee the conduct of this research.

## The Fetal Tissue Transplantation Debate

During the 1988 NIH panel hearings and during congressional debate concerning fetal tissue research, a common list of ethical questions was addressed:

- Is fetal tissue transplantation ethically acceptable? Should the integrity of a human fetus place it in a class entirely separate from that reserved for other biologic gifts, such as blood, kidneys, and hearts?
- Should fetal tissue acquired from elective abortions be exempted from research uses? Should a woman not be allowed to play contradictory roles as agency in a fetus's death and as proxy to authorize donation of the fetus's tissue?
- Must a pregnant woman give consent to allow her fetus's tissue to be used for research purposes?
- Should a woman be permitted to abort a fetus to provide transplantable tissue for a relative?
- Will fetal tissue transplantation indirectly encourage women to choose abortions? If so, is this effect ethically permissible?

It is not the task of ethical analysis to answer these questions definitively. Various polling organizations have already gauged popular opinion, and the results are not surprising. A survey of college students indicates support for federal funding of fetal tissue research and opposition to the idea of women designating specific fetal tissue transplant recipients.[24] Nor have centuries of ethical analysis created political consensus. Legislators, governors, judges, and the electorate may long continue to debate the wisdom of *Roe versus Wade*, the public funding of family counseling, and the public's access to experimental procedures. In 1989, the Stanford University Medical Center Committee on Ethics, composed of 48 representatives of the university community, agreed that human fetal tissue research, when subject to the legal rules of the Uniform Anatomical Gift Act (UAGA) and a prohibition against a woman's designating specific recipients of fetal tissue, is ethically acceptable.[25]

Our ethical analysis will suggest a responsible direction for public debate about fetal tissue transplantation, which operates under the assumption that in the prevailing legal climate of the United States, abortion performed under informed consent is ethically acceptable.

### *Is a Fetus a Person?*

Whereas abortion may be ethically acceptable, the actual practice remains inherently distasteful to most persons. In fact, without such a prevalent distaste for abortion, this entire discussion would be moot. Abortions would be neutral events, and fetuses would be neutral products of those events, openly accessible to researchers and clinicians.

The equivocacy of personhood is a central reason for this distaste. When during gestation does a fetus become a person, with accompanying rights? How do we identify a fetus as dead or alive, viable or nonviable? Do the answers to these questions have any bearing on the

postabortion use of fetal tissue? These questions are best approached at three points during fetal existence:

- Personhood after fetal death is accepted by most ethicists and legal scholars as the easiest to assess.[26] Regardless of its antemortem status, a dead fetus claims the same rights as a dead person. As with any human cadaver, the closest relative or guardian of the deceased has whole authority over the disposition of the fetal cadaver.
- Personhood in utero, before viability, is difficult to assess ethically, largely because fetal viability is difficult to define medically. Medical judgment generally labels previable any fetus less than 24 weeks' gestational age (about 500 grams), estimated by ultrasonic measurement of the fetal anatomy. At this stage, it is generally agreed that, even with extraordinary medical treatment, fetal lungs are incapable of operating independently. Most states permit elective abortions to be done on fetuses under 20 weeks' gestational age. This definition was established, however, before the successes with intra-alveolar surfactant treatment and extracorporeal mechanical oxygenation, which now enhance the long-term survival of infants weighing less than 750 grams (26 weeks' gestation).
- Fetuses ex utero and alive create the greatest challenge to an ethical critique of fetal tissue transplantation. Abortion procedures depend on the gestational age at which they are done. During the first trimester (before 12 weeks), a fetus is removed by suction and curettage techniques. During the second trimester, a fetus can be delivered live after the induction of labor, or more commonly, the fetus can be dismembered in utero and the fetal parts manually extracted. The second-trimester procedures sometimes, although rarely, produce fetuses whose cardiovascular and brain-stem functions remain operative for several hours ex utero.[27] More than 90% of abortions performed in the United States are done during the first trimester,[28] and most current research with transplantation for Parkinson's disease and diabetes mellitus uses tissue from fetuses aborted during the first trimester.

Ethical problems exist only for those rare second-trimester abortions that produce whole, live fetuses. It must be assumed that during this time period, when the fetus ex utero is alive, it claims the concomitant rights of personhood. Strong ethical and legal principles argue against the use of tissue from fetuses during this period. Under the principles of the Nuremberg Code and the Helsinki Declaration, nontherapeutic experimentation without a subject's informed consent is unethical, particularly if that experimentation is harmful to the individual.[29] United States judicial precedent argues against the authority of parents or guardians to consent by proxy to the nontherapeutic use of a child's organs to save the life of another child.[26] (The state assumes the role of *parens patriae* to resolve a conflict of interest between the emotional needs of the guardians and the life-claiming needs of the child.) Although not absolute, the same legal principle can be used to argue against the donation of a kidney from a dying anencephalic infant.

It follows logically, therefore, that the transplantation of tissue from live fetuses ex utero should be prohibited. Tissue from second-trimester abortions should, however, be available for transplantation immediately after fetal death has been declared by a qualified physician. A woman should be allowed to consent to the use of tissue from a dead fetus during the antemortem period, and there is no ethical proscription against subsequently informing a researcher of the impending death.

*Bad Science*

Beyond the debate about fetal personhood, the following arguments against the use of fetal tissue for transplantation to living humans are commonly presented:

- The results of animal and human research trials have not been encouraging, medical alternatives to fetal tissue transplantation exist, and the potential benefits of such transplantation do not reduce mortality. A careful review of the literature by a British ethicist concludes that "the case for utilization of human foetal pancreas in transplantation is in no way strengthened by the results of animal experimentation."[27(p58)] Medical therapy for parkinsonism, diabetes, and hematologic disorders is available, and unlike heart-lung and kidney transplants from adult cadavers, fetal tissue transplants do not represent immediate, life-saving treatment.

Although the claims of possible benefits from fetal tissue transplantation are admittedly guarded, we should not prohibit continued research and clinical trials in this field. The Helsinki Declaration, which demands that successful trials in animals precede human trials of experimentation, allows clinicians and researchers to judge the meaning of the word "success." The most important element of an experimental trial is an effective process for affording the transplant recipient full and informed consent. Perhaps scientific critics of fetal tissue transplantation should be welcomed to review this informed consent process, but they should not ask for artificial means (such as a blanket moratorium) to slow the pace of clinical research.

- The scientific use of fetal tissue welcomes abortion as "good," a necessary precursor to advances in medical therapy. By extension, opponents claim, society would be supporting the institution of abortion. This runs directly against a prevailing American sentiment that prefers to condone abortion, not to afford it any independent admiration.

"Science, since people must do it, is a socially imbedded activity," writes Stephen Jay Gould in *The Mismeasure of Man*, a historical treatise that argues for social accountability in science.[30(p21)] Scientists and clinicians make implicit social judgments with every primate experiment, every drug toxicity screen, and every private research institution newly incorporated. There is no ethical proscription against American scientists implicitly supporting women's access to abortion procedures. Those researchers and physicians who object to abortion are under no obligations to participate in procedures associated with fetal tissue transplantation.

*Encouraging Elective Abortions*

According to the most-often-voiced argument against fetal tissue transplantation, the life-enhancing potential of the procedure may encourage more abortions. Opponents argue that by adding something "good" to a distasteful procedure, fetal tissue transplantation may encourage more women to opt for abortions. Worse yet, the marketability of fetal tissue may encourage indirect ways of increasing the abortion rate. Hypothetical slippery slopes run rich in this argument. Imagine the following plausible scenario:

In mid-1993, a phenomenally successful procedure to treat male-factor infertility requires the transplantation of testicular cells from fetal tissue of more than 14 weeks' gestation. (Elective abortion and infertility therapy share common properties: neither are funded by public insurance, and neither are recognized as life-threatening.) Less than half of all aborted fetuses are eligible to provide such tissue, and because of the approval by the Food and Drug Administration for mifepristone (RU 486), the incidence of elective abortions nationwide is declining. A shortage of tissue develops. Meanwhile, private medical corporations market the treatment to thousands of infertile men, creating an increased demand. Because of these pressures, the incidence of abortion increases.

The claims are threefold: that the abortion rate will increase, that an increasing abortion rate is wrong, and that the influences that will create this increasing abortion rate are wrong. The first claim is wildly speculative, but for the purposes of this ethical analysis, it may be conceded. The second claim has already been discussed: namely, that although abortion may be distasteful, its exercise in the United States is ethically acceptable. The third claim requires further consideration.

*Fetal Tissue Donation and Decision-making Autonomy*

To understand why the third claim of the argument is untenable, we must first define "influence." Faden and Beauchamp depict a graded continuum of influences on a patient's decision-making process.[31] The goal of their analysis is to identify what they call "substantially controlling influences" that unduly compromise autonomous decision making. At one end of this continuum is rational persuasion, the art of convincing the family of a febrile patient with mental status changes, for example, to provide consent for a lumbar puncture. Persuasion falls entirely within ethical boundaries because it is a noncontrolling influence. At the other end of the continuum is coercion, strictly defined as any irresistible threat that causes a person to do something they otherwise would not do. Coercion exists when a researcher threatens to fire an employee unless that employee participates as a research subject. Coercion is ethically impermissible.

The middle ground on the continuum is manipulation, which may or may not be "unduly controlling." The US Public Health Service was unethical when it unduly manipulated (some claim "exploited") economically deprived men to participate in the Tuskegee (Alabama) syphilis experiments by providing irresistible offers of free food, medication, and burial assistance.[32] A professor would be within ethical boundaries, however, in offering extracredit points to students who enroll as research subjects because the offer is both welcome and (under the provision perhaps that a "B" not be convertible to an "A") resistible.[31]

Certainly any financial reimbursement for fetal tissue donation is ethically unconscionable because it may substantially compromise a woman's decision-making autonomy. Although welcome, it may not be effectively resistible. The UAGA's existing prohibition against the sale of human organs should be extended to protect fetal tissue donation from such controlling influences.

Could the altruistic thought of fetal tissue transplantation impose a controlling influence on a pregnant woman's decision about abortion? If a family member with diabetes or Parkinson's disease stands to benefit from a fetal tissue transplant, a woman might find reason to abandon fundamental beliefs against abortion. This effect may be real, but it is not coercive because the option of abortion is freely resistible and nonthreatening. There is one scenario, however, that could foster undue manipulation. If the woman were allowed to designate a specific person as the recipient of the transplant, the option of abortion may become effectively irresistible. In the case of permitting designated recipients, fetal tissue transplantation may be considered a substantially controlling influence over a woman's decision-making autonomy.

There must be safeguards in the donation process. First, financial incentives for fetal tissue donation should be declared explicitly illegal. Second, a woman should not be allowed to designate a specific recipient or group of transplanted tissue for her aborted fetus's tissue.

## Ethical Dilemmas

Now that the scientific support, the political reality, and the ethical acceptability of fetal tissue transplantation have been established, new ethical issues arise. The Department of Health and Human Services will soon be creating guidelines and "safeguards" governing the use of fetal tissue. Many new questions must be addressed: How should fetal tissue be procured? Which transplant recipients should be given preference, and which diseases should be given preference? What type of informed consent ought to be obtained? Who should be responsible for obtaining informed consent from the tissue donors?

*Managing Fetal Tissue*

Tissue from an aborted human fetus deserves the same respect and dignity afforded tissue from an adult cadaver. A fetus possesses moral integrity, unlike blood or a kidney, and as such should be respected as a donor, not as a gift. By this definition, all fetal tissue donated for scientific research may be governed by the same ethical principles that govern the use of cadaveric organs.[33] In more than 95% of cases, an adult trauma victim, like a deceased fetus, contributes no direct consent to authorize organ donation. Instead, the UAGA designates the closest

relative, usually the parents of the deceased, to act as proxy for such consent. As such, any fetus whose death is unavoidable, as in the cases of spontaneous abortions and ectopic pregnancies, should be treated as would the body of a deceased adult.

Likewise in "avoidable" cases of elective abortion, fetal cadavers should be afforded the same dignity, neither more nor less, as that of adult cadavers. Indeed, some suggest that fetuses from elective abortions deserve greater protection from research use than do adult cadavers. Nolan extends this argument to conclude that fetuses from elective abortions should be ineligible as sources of transplantable tissue.[34] She argues that any woman who acts as an "agency of death" of a relative should not be able to act also as a decision-making proxy for that relative's organ donation. The fetus, in this model, is a murder victim, not an accident victim. Therefore, she suggests, only tissue from spontaneous abortions and ectopic pregnancies should be used in research.

To answer this argument, we must first understand that it is based on a moral opposition to the abortion procedure itself. It assumes that abortion is murder and that affording any authority to the murderer is wrong. The prevailing legal climate, however, "acquits" a woman choosing abortion of the charge of murder. Against that simple premise, the argument cannot stand.

But even if we accept the assumption that the fetus is a murder victim, the argument against the use of elective abortuses fails. Murder victims, like accident victims, are eligible organ donors under the provisions of the UAGA. The only prohibition, then, would be against asking the "agency of death" for consent. If the woman were to be viewed as a murderer, authority for donating tissue would rest in the hands of the nearest surviving relative—the woman's husband, the fetus's father, the woman's child—or, if one is neither available nor competent, authority would rest on a court order. The result (that each abortion require a search for the appropriate consenting adult) is absurd, but it does not prohibit the use of tissue from elective abortions. Instead, it makes the process cumbersome for clinicians and medicolegal staff, and it unjustly alienates women.

The UAGA, which has been active in most states since 1985, dictates guidelines for the treatment of any donated human tissue, including the following:

- No monetary compensation or services, including medical services, should be exchanged for donor tissue. The construed purpose of this guideline for fetal tissue transplantation is to protect a woman from undue manipulation during her decision to terminate a pregnancy.
- Informed consent should be obtained from the closest competent donor family member. By law, this gives the woman and the child's father equal power to authorize consent.

Under these guidelines, donors are allowed to designate recipients of donated organs, and the handling of donated tissue is not discussed. With this in mind, we recommend two additions to the guidelines established by the UAGA, designed specifically to address the sensitive issues of abortion and fetal tissue donation:

- The donor and donor family should be disconnected from the process of choosing the transplant recipient. As previously discussed, this prevents unjust consequences for recipients and undue influence on the donor families.
- Donor tissue should be acquired discreetly and rapidly. The most recent review of the literature indicates that the therapeutic function of grafted dopaminergic cells is greatest when the donor tissue is fresh.[35] Nonetheless, the tissue deserves the respect in handling that would be afforded any human cadaver. We recommend that each clinical facility providing donor fetal tissue include in its code a provision for Institutional Review Board oversight of fetal tissue procurement.

*Selecting Recipients*

The field of fetal tissue transplantation has yet to face a daunting obstacle that for years has complicated the field of adult organ transplantation: the inadequate supply of needed tissue. Current projections estimate the yearly incidence of elective abortions at about 1.5 million,[28] and the maximum estimate for the Parkinson's disease population of the United States is just under 510,000.[36] Should current experiments become remarkably successful with Parkinson's disease, the supply of transplantable tissue should be adequate. Furthermore, many researchers suggest a future in which one aborted fetus may be used to create multiple cell lines that have the potential to treat hundreds of patients. Nonetheless, if new protocols with other diseases prove fetal tissue transplantation useful in the treatment of larger patient populations such as those with diabetes or leukemia, the problem of rationing fetal tissue may become real.

Given that recipient populations for fetal tissue therapy are largely hypothetical, creating criteria now to help allocate donor tissue in the future is premature. Useful themes exist, however, in the current systems for choosing recipients of pediatric and adult organs. The process of organ procurement and allocation is orchestrated by the National Organ Procurement and Transplantation Network, established by Congress in 1984. Criteria to exclude possible recipients are social and medical: advanced age, inability to pay, lack of psychosocial support, psychiatric illness predisposing to noncompliance with a strict medical regimen, incompatible blood type, systemic infection, degree of organ failure, and a list of other medical conditions that varies with the type of transplantation. Ad hoc amendments to these criteria are often made, based on subjective judgments of social appropriateness or of the degree of medical emergency.[37] The social criteria are clearly the most ethically problematic, but they have withstood more than a decade of debate in the bioethics literature. These criteria can be debated on the same grounds regardless of the origin of the donated tissue.

Anticipating the arrival of fetal tissue transplantation

as a therapeutic reality, we suggest that any recipient selection scheme should include the following:

- A federal mandate to the National Organ Procurement and Transplantation Network to create a national registry of possible fetal tissue recipients.
- An annual conference of fetal tissue researchers, physicians, and surgeons to determine medical exclusion criteria specific to each of the newly approved therapies.
- The inclusion of bioethicists, psychiatrists, legal experts, and organ recipients in the annual conference to participate in the creation of exclusion criteria that are nonmedical.
- A prospective study of all fetal tissue recipients to accumulate data that will further inform the annual conference.

*Requiring Informed Consent*

Because a human fetus is more than a vestigial organ from the female body, researchers should not be allowed to acquire fetal tissue without a woman's consent. Under UAGA regulations, the fetus should be treated as donor and the pregnant woman as "next of kin." As already explained, the act of abortion does not disqualify her as an appropriate proxy for decision making regarding donation.

Under these definitions, informed consent for using fetal tissue in transplantation should be obtained from a pregnant woman before she has an elective abortion. Noting that the UAGA's definition of "next of kin" includes the father, the NIH advisory committee in 1988 added that fetal tissue should not be used if the father objects, "except in cases of incest or rape."[38] It is unnecessary, both from an ethical perspective and from a practical perspective, for researchers or transplant surgeons to obtain this consent in person. The best requester is a good communicator and counselor. In the area of cadaveric organ transplantation, the requester is usually a primary care physician, a primary care nurse, an emergency department physician, or an experienced liaison person from a local organ procurement organization. Similarly, fetal tissue researchers may opt to provide informed consent information through either physicians or an organ procurement organization. Once consent is obtained, the tissue should be removed from the operating suite by an authorized representative of the fetal tissue transplant team.

Informed consent should be requested only in cases in which there is a reasonable chance that the fetal tissue will be used for transplantation purposes. Given the currently low demand for such tissue, it would be unreasonable to require that all women seeking abortions be counseled about fetal tissue transplantation.

*Ethics of Persuasion*

Could the demand for fetal tissue encourage indirect inducements to abortion? As explained earlier, the supply of fetal tissue from elective abortions exceeds the current demand. But even if the demand increases dramatically, the feared inducements to increase abortion rates may likely be unsuccessful. After ten years of legal requirements and millions of dollars in educational efforts, the attempt to increase organ donation rates of adult donors has been largely unsuccessful. It is unlikely that less direct attempts to increase abortion rates would be more successful.

Even if successful, there is nothing morally wrong with providing information about fetal tissue transplants to influence a woman's decision making. This is the sort of rational portrayal of information that Faden and Beauchamp call persuasion.[31] Photographs of bloody fetuses have strong persuasive power, but their issuance to pregnant women contemplating abortions is not morally wrong. Similarly, the potential that tissue extracted from fetuses may improve the lives of persons with Parkinson's disease offers persuasive information that should not be peremptorily excluded from a woman's decision-making process.

One recently proposed piece of legislation threatened to limit such free exchange of information. Congressional bill HR 2507 explicitly exhorted a woman to identify the influences on her choice to have an abortion to ensure that fetal tissue transplantation is not one of those influences. The bill's language required physicians to be participants in this scrutiny.[23] Women get pregnant for many reasons, but no one suggests the need to monitor every woman's motivations to get pregnant. No legislator seriously proposes that pregnant women seen in publicly funded maternal health clinics sign documents attesting that their decision to have a child is "separate and independent" of economic, medical, or other external influences. Extending the same argument, no legislator should seriously propose to scrutinize a woman's decision-making process to terminate her pregnancy.

If the need for fetal tissue becomes as great as the current need for cadaveric organs, state governments may consider expanding the required request legislation to include women seeking abortions as a mandated population for organ donation requests. Persuading women to donate fetal tissue is not only ethically permissible, it may prove to be ethically necessary.

## Suggested Guidelines for Fetal Tissue Transplantation

Based on the analysis of the ethical challenges to the use of fetal tissue, we suggest that fetal tissue transplantation is an ethically appropriate activity when subject to the following stipulations:

- Fetal tissue derived from dead fetuses resulting from elective abortions should be included under the principles of the Uniform Anatomical Gift Act.
- Financial incentives to a donor's family, physicians, researchers, or any other party involved in the donation of fetal tissue should be prohibited.
- Women donating fetal tissue should not be permitted to designate specific recipients of that tissue.
- Informed consent specific to the use of fetal tissue for research and transplantation should be made available to all women whose aborted fetuses may be used for the purposes of transplantation.

- Each clinical facility providing donor fetal tissue should mandate in its code Institutional Review Board oversight of fetal tissue procurement.
- The National Organ Procurement and Transplantation Network should include fetal tissue transplant recipients in its national registry.

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